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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/742,803 | 12/19/2000 | Gary R. McLuen | NEI-00104 | 7285 |

28960 7590 12/12/2007
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| EXAMINER |
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HANDY, DWAYNE K

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| ART UNIT | PAPER NUMBER |
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1797

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| MAIL DATE | DELIVERY MODE |
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12/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/742,803 | Applicant(s) MCLUEN ET AL. | |
| | Examiner Dwayne K. Handy | Art Unit 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-30,35-38,40,42 and 44-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-30,35-38,40,42 and 44-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 27-29, 35-38, 40, 42, 44 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by McGraw et al. (5,368,823).
3. Claims 27-30, 35, 36, 38, 45-48 and 50-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Zuckerman et al. (5,240,680).
4. Claims 27-30, 35, 36, 38, 45-48 and 50-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Cargill et al. (5,609,826).

These rejections were applied or upheld in the previous Office Action (mailed 3/21/07). They remain in effect and apply to new claims 50-52 as well. Please see Response to Arguments below.

Response to Arguments

5. Applicant's arguments filed 9/24/07 have been fully considered but they are not persuasive. Applicant has argued that McGraw fails to anticipate the instant claims because McGraw does not show teach a direct fit between the vial (column) and cartridge (bulkhead). This argument is beyond the scope of the claims as written. As

noted in the previous Office Action (paragraph 7); the vial of McGraw still meets this limitation (as do new references Zuckermann and Cargill). The claim as currently written does not include the hole of the cartridge or even the cartridge. Applicant has not claimed the cartridge. Applicant has claimed a "having an exterior dimension to fit directly within a receiving hole of a cartridge". Therefore, any vial that has an exterior dimension that allows it to fit directly in a hole will meet this limitation. Applicant is attempting to limit an element of the claimed device - an exterior dimension of the vial - by using another, unclaimed element - a cartridge hole. The Examiner submits that there is no structural limitation that is provided by this phrase. The vials/vessels of the prior art have a dimension that would allow them to fit directly into the receiving hole of a cartridge in a pressure tight seal. Therefore the vials of the references meet that limitation.

6. Applicant has argued that Zuckermann does not teach a solid support or the pressure tight seal. As noted above, the pressure tight seal is beyond the scope of the claim. The claim merely requires that the vial have an exterior dimension to fit directly in a receiving hole. This is what Zuckermann shows in Figure 3. The Examiner previously noted that Zuckermann does not show the solid support but their use is disclosed in columns 2 and 3.

7. Applicant has argued that Cargill does not teach a solid support or the pressure tight seal. As noted above, the pressure tight seal is beyond the scope of the claim. The

claim merely requires that the vial have an exterior dimension to fit directly in a receiving hole. This is what Cargill shows in Figures 6-8. The Examiner previously noted that Cargill does not show the solid support but their use is disclosed in column 2 and at the end of column 7.

8. Applicant has also argued that because McGraw recites the use of a vacuum to draw the chemical through the column (McGraw, col. 2, lines 17-22), then this excludes the presence of a pressure tight seal (Applicant's Arguments, page 9, lines 13-22). The Examiner respectfully disagrees and notes that McGraw is not using the vacuum to seal the vial to the bulkhead, but instead is simply using vacuum to empty the contents of the columns into the exit basin (17). Furthermore, the Examiner submits that if there wasn't a pressure tight fit between McGraw's vial and the opening (15) in the bulkhead (16), then the vacuum could not function to draw the chemicals through the columns to the exit basin (17).

9. Applicant has argued that the Examiner has unilaterally dismissed the pressure tight seal limitation (Arguments, page 9, lines 23-33). This is not the case. The Examiner has stated that the Applicant's arguments directed to the limitation of "an exterior dimension to fit directly within a receiving hole of a cartridge". This limitation is based upon an element – the receiving hole of the cartridge – which is not part of the claimed device. Therefore, the limitation of the "exterior dimension to fit directly within a receiving hole of a cartridge" is extremely broad. The dimension could be any shape

or size - as long as the element is capable of fitting in a hole of a cartridge, it will meet this claim. Applicant has argued that the references do not show a vial placed directly into a cartridge, therefore, the vials do not meet this limitation. This is incorrect and the reason for Examiner's assertion that the argument is beyond the scope of the claim.

For this particular limitation, the reference does not have to show the vial directly in a cartridge; it simply has to show a vial having "an exterior dimension to fit directly within a receiving hole of a cartridge". The Examiner submits that the lower portion of the vials in each of the references cited show just this feature – a round portion that could fit directly into a cartridge hole. See Figures 5 and 6 of McGraw, Figures 2 and 3 of Zuckermann, and Figure 2A of Cargill.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DKH
December 10, 2007



JAN LUDLOW
PRIMARY EXAMINER